International Hearing Society Perspective on Patient Safety and Outcomes

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Disclosures

- I serve as owner of Beall, Inc., a hearing aid practice.

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Disclosures

- President, International Hearing Society
- Member
  - Academy of Doctors of Audiology
  - American Academy of Audiology
  - American Speech-Language-Hearing Association
  - Hearing Healthcare Alliance of Ohio

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IHS opposes OTC hearing aids intended to address bilateral, gradual onset, mild-to-moderate age-related hearing loss

- Those presenting with hearing loss cannot self-diagnose or self-treat
- Difficulty limiting who would purchase devices → "intended use" v. actual use
- Missed or delayed diagnosis can lead to "irreparable damage, further deterioration of hearing, or increased risks of surgery for the hearing aid user" *(FDA to Mead Killion, 2004)*
- Missed diagnosis of other medical conditions that could be medically or surgically treated, or inappropriately purchasing hearing aids
- Would upend the state licensure and regulatory structure
- Eliminates essential consumer protections and safety measures
- Would likely lead to a reduction in device quality and patient outcomes
- Would open the door to unscrupulous practices and providers and significant consumer harm – why the rule was originated in the first place!

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Can an individual self-diagnose, self-treat, and self-monitor mild-to-moderate age-related hearing loss?

Mild-to-moderate age-related hearing loss indicators

- Bilateral, sensorineural hearing loss
- Pure tone average loss between 26 and 60 dB
- Gradual progression of loss
- Sloping loss--greater loss for high frequencies
- Reduced dynamic range for affected frequencies

Other possible conditions

- Cerumen impaction
- Vascular conditions
- Otosclerosis
- Cholesteatoma
- Noise-induced hearing loss
- Acoustic neuroma
- and more

IHS Red Flag Survey Results

FDA Red Flag Condition
Visible congenital or traumatic deformity of the ear
History of active drainage from the ear within the previous 90 days
History of sudden or rapidly progressive hearing loss within the previous 90 days
Acute or chronic dizziness
Unilateral hearing loss of sudden or recent onset within the previous 90 days
Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz
Visible evidence of significant cerumen accumulation or a foreign body in the ear canal
Pain or discomfort in the ear

How often do you refer, or attempt to refer, a patient for medical reasons?	
Occasionally	39%
Often	30%
Routinely	28%

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Source: IHS Medical Referral Survey, 2014

Can an individual self-diagnose, self-treat, and self-monitor mild-to-moderate age-related hearing loss?

Diagnose/Assess

- Patient history, including identification of related medical conditions, i.e. diabetes
- Audiometric testing
  - Pure tone audiometry: pure tone air and bone conduction testing with masking, thresholds of discomfort
  - Speech testing: speech awareness and/or speech reception threshold tests, speech discrimination test, establishing MCL and UCL
- Otoscopic examination
- Screening for FDA Red Flags

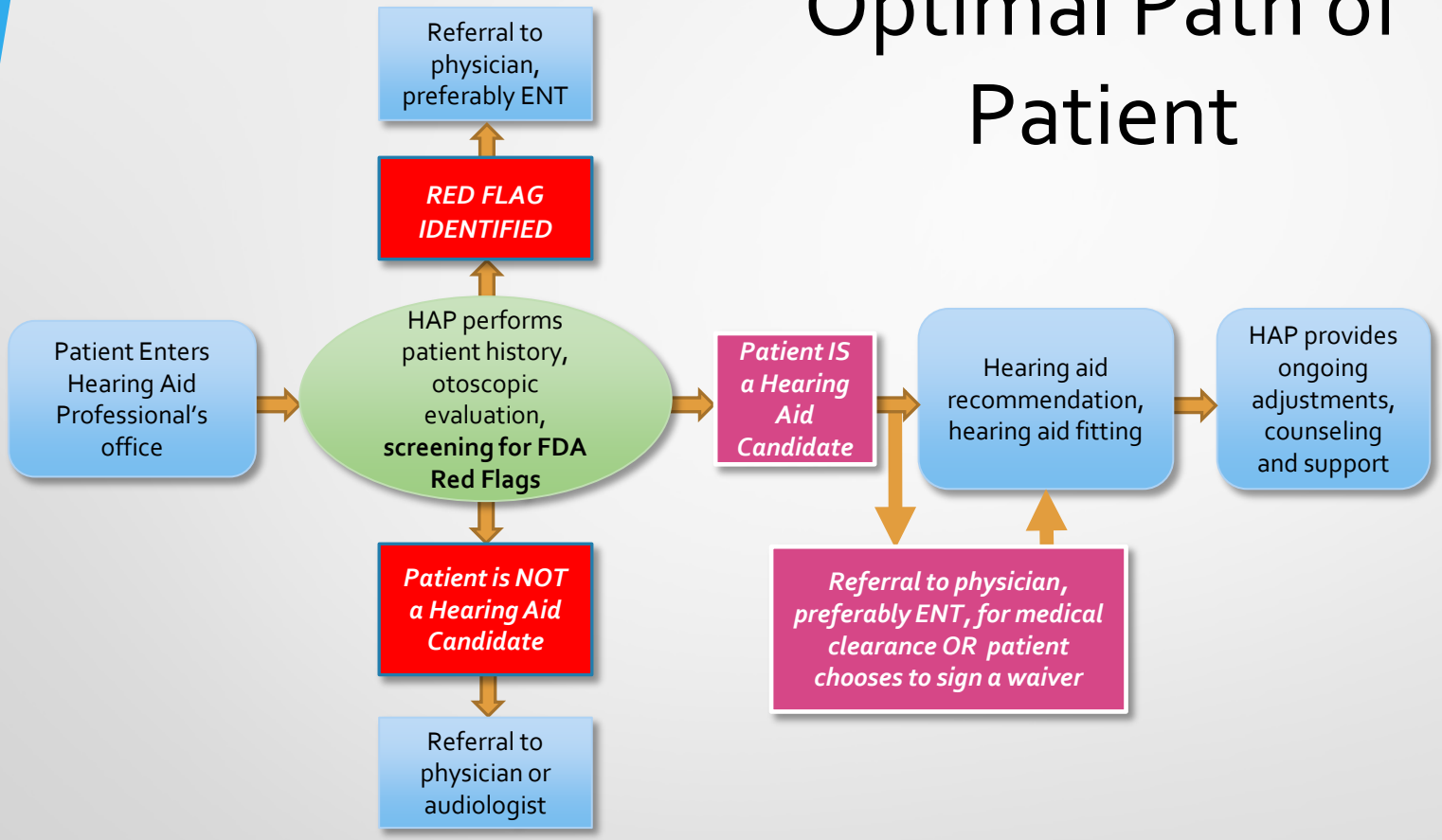
Identify and understand type and degree of hearing loss and determination of whether medical referral is appropriate or whether he/she is a hearing aid candidate.

Treat

- Determines hearing aid candidacy, or alternately refers for medical, surgical, or other intervention
- Hearing aid "treatment"
  - Selecting optimal hearing aid
  - Programming hearing aid for frequency response and dynamic range
  - Hearing aid fitting
  - Performing validation and verification measurements
  - Fitting/programming adjustments as needed
  - Training on device functionality/use
  - Setting expectations, counseling, and aural rehabilitation
  - Identifying suitable assistive listening devices

Ensure patient receives the appropriate treatment for his/her hearing loss, which may include a hearing aid. The hearing aid should be customized to ensure proper fit and function, and the patient should receive counseling on its use and aural rehabilitation strategies.

Optimal Path of Patient



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Impact of proposal on other populations

- Those with underlying pathology
- Children
- General population (those under 60)
- Those with more severe loss

FDA's historical perspective on the role of hearing aid providers

Fed. Reg., Vol 42, No 31, 2/15/1997

"The Commissioner recognizes that the professional and patient labeling regulations and restrictions on the sale of hearing aids are only a partial solution…"

"State and local licensing laws, as administered by State and local agencies, are the appropriate legal mechanisms for establishing minimum competency standards…"

"Such licensing statutes thereby protect the public against unfit and inept practitioners…"

FDA already has it right

FDA letter to Etymotic Research, 2004

"These hearing aid restrictions were recommended in 1976, when the FDA's Interdepartmental Task Force on Hearing Aids found that the misevaluation of a patient's need for a hearing aid and the subsequent sale of a hearing aid that is ineffective and possibly unsafe for its intended use were major problems in the hearing aid delivery system. In its report to the FDA, the Task Force cited studies indicating that patients bought hearing aids when their hearing loss required medical treatment."

"FDA continues to believe that the safe and effective use of hearing aids depends on the collateral measure of a physical examination to ensure that a hearing aid, rather than medical or surgical treatment, is the appropriate solution to a particular person's hearing impairment."

FDA already has it right

FDA Hearing Aid Rule Preamble, 1977

"FDA has judiciously exercised its rulemaking authority to provide for minimal Federal intervention consistent with essential protection of the public health in the delivery of hearing aid health care services. This approach recognizes the limitations of FDA statutory authority in dealing with such factors as the cost of a hearing aid and the inadequacy or absence of State licensing laws."

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Top Ten Reasons for Hearing Aid Delight

1. The Hearing Care Professional
2. Continued Connection
3. Verification & Validation
4. Experimentation
5. Strong Recommendation
6. Counseling
7. Evaluation
8. Professionalism
9. Motivation
10. Hearing Aids Work

Source: "Top Ten Reasons for Hearing Aid Delight: Strategies for Success," Hearing Industries Association, 2011

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Hearing aid use is on the rise

	2008	2014
% of Americans with hearing aids	2.8	3.2
% of Americans with hearing difficulty who own a hearing aid	24.8	30.2
Average age of hearing aid purchaser	68.9	63.3
% of adults who reported having a hearing screening during a physical exam	15	23
Hearing aid satisfaction	74%	81%
% of Hearing aids in the drawer	12	3

Source: MarkeTrak VIII and IX, Better Hearing Institute, 2008 and 2014

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IHS on PCAST Recommendations

- Reject proposal to create over the counter classification of hearing aids
- Reject proposal to eliminate 2013 Guidance on PSAPs; instead adopt 2013 Guidance

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